(In)accuracy of blood pressure measurement in 14 Italian hospitals.

UNIVERSITÀ DEGLI STUDI DI TORINO

Title: (In)accuracy of blood pressure measurement in 14 Italian hospitals.

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Key words: Blood pressure measurement; Blood pressure management; healthcare quality; hospital care; cross-sectional design; Italy.

Running title: Blood pressure measurement accuracy in hospitals.

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Word count: 2546.

Abstract

Objectives: The diagnosis and control of hypertension depend on accurate measurement of blood pressure (BP). The literature on the accuracy of BP recording by health professionals is however limited, and no study directly interviewed patients in the hospital setting. This multicenter cross-sectional study aimed at evaluating the compliance to current recommendations on BP measurement by health professionals directly from patients, and to investigate potential predictors of higher quality in BP recording.

Methods: A trained nurse interviewed a random sample of adult patients hospitalized for an ordinary admission (except in the emergency room) lasting more than one night, without mental disorder, who had their BP routinely measured by the hospital personnel less than 3 hours before. The questionnaire contained 15 items on the main procedures that are common to current guidelines.

Results: Fourteen public hospitals from seven regions of Italy participated, and 1334 questionnaires were collected. Nine of the recommended practices were followed in the majority (>70%) of BP recordings, while some others were infrequent or rare: in 98.6%, 82.2% and 81.1% of the participants, respectively, the arm circumference was never recorded, BP was measured only once, and BP was never recorded in both arms. Overall, >=10 recommended procedures were followed during 33.4% recordings. At multivariate analysis, physicians were less likely than nurses to provide a more accurate BP measurement.

Conclusions: The operator's compliance to some recommendations in BP measurement is unacceptably low. This survey provides detailed indications for medical directors on the procedures and settings to prioritize in educational programs, which are strongly needed.

Condensed Abstracts

The diagnosis and control of hypertension depend on accurate measurement of blood pressure (BP). The literature on the accuracy of BP recording by health professionals is however limited, and no study directly interviewed patients in the hospital setting. This multicenter cross-sectional study showed that the operator's compliance to some recommendations in BP measurement is unacceptably low. This survey provides detailed indications for medical directors on the procedures and settings to prioritize in educational programs, which are strongly needed.

Key words: blood pressure; blood pressure measurement; educational program.

Introduction

The diagnosis and control of hypertension depend on accurate measurement of blood pressure (BP). However, the determination of BP involves problems of accuracy because of inherent biological variability, even in the short term [1, 2], the tendency of BP to increase when measured, particularly in the presence of a clinician (white coat effect) [3], and inaccuracies related to suboptimal technique [4].

Several authors repeatedly highlighted the potentially large misclassification and clinical consequences for patients of low-quality (or casual) BP measurement [4-10], and a number of studies investigated the reliability of BP measuring devices [11, 12] or compared the impact of different measurement protocols [9, 13, 14]. However, the literature on the accuracy of BP recording by health professionals is limited [15-19]. Moreover, four of the five studies assessed BP measurement from health professionals only (with potential reporting bias) [15-17, 19]; three were carried out into primary or ambulatory care settings [15, 16, 18], and only two were multicentric [15, 17]. So far, no study evaluated the accuracy of the determination of BP directly from hospital patients, and no study investigated the potential predictors of an inaccurate BP measurement, which may be essential to identify proper solutions.

We carried out a cross-sectional survey on several Italian hospitals from different regions, in order to evaluate the compliance to current recommendations on BP measurement by health professionals. We interviewed both patients and health professionals on several components of the recording of BP and equipment status, and investigated potential predictors of a higher quality in BP determination.

Methods

We asked for the participation of the academic centers of eight regions of the South, North and Center of Italy. Although we recommended that hospitals of different size (number of beds) should have been included, no exclusion criteria were applied for hospitals, except for the approval of the local Ethics Committee (the initial approval was granted from the coordinating center in Chieti). The protocol was also endorsed by the Italian Nursing Federation (IPASVI).

From April to December 2011, in each participating hospitals, a previously trained nurse (employed in a different facility) interviewed a random sample of patients who had their BP routinely measured by the hospital personnel no more than 3 hours before. Patients could be included if they were aged 18-80 years;

hospitalized for an ordinary admission lasting more than one night; had no mental disorder; provided signed informed consent.

Based upon the potential clinical relevance of BP measurement, most wards were included: i.e. specialized wards on eye or ear disorders were excluded. Also, the Emergency Department was not included because of the frequent time shortcoming in life-saving techniques which may balance a lower accuracy in BP measuring.

A complete list of the measures considered and information collected is reported in the Supplemental online appendix (section 1). The structured interview included a few items collecting information on the hospital unit, the adequacy of the technical equipment for BP measuring; patient's age and gender. Also, the questionnaire contained 15 items specifically aimed to evaluate the degree of adherence to guidelines during the measurement of BP. The questionnaire was designed to include items on the main procedures that are common to all current recommendations [20-22], and an initial 20-item version was validated in a pilot survey on 50 patients from the coordinating center. Redundant or less relevant items were dropped and wording was slightly revised (Supplemental online appendix – section 2).

A computer-generated random table, provided by the coordinating center, indicated three consecutive days for data collection in each hospital, and all patients staying in the hospital during that days were interviewed. We recommended that different wards were included in the three days, so that no interviews were made in the same ward more than two consecutive days. To further reduce the likelihood of opportunistic behaviors, no ward was informed before the arrival of the interviewer.

To derive a proxy of the overall adherence to BP measurement guidelines, we created an global quality score assigning 1 point for each “positive” answer (i.e. BP was measured twice within a few minutes) and 0 points for each negative answer (i.e. BP was measured only once). Higher scores indicated higher adherence to guidelines during BP recording: the maximum possible value – 15 – meant that all recommended procedures were followed during BP measurement.

We then evaluated the potential predictors of overall guidelines adherence using both multilevel mixed-effects linear and logistic regression [23]. In both cases, the cluster variables were region and hospital (both assuming an independent correlation structure; however we repeated all models setting an exchangeable correlation structure, with marginal increases in standard errors and no qualitative change). All recorded

covariates (gender, age, health professional recording BP, and ward) were included in all models a priori, although the number of wards included as dummy variables was reduced after the observation of no substantial differences among the wards with fewer observations and to avoid instability of the estimates. Multicollinearity, interactions and higher-power terms were tested for all covariates. To obtain the dependent variable of the logistic model we dichotomized the overall adherence score using various thresholds: 8 (the median value), 9, 10, 11 or 12 “positive” answers. For each threshold, we fit a separate mixed model. Given that the results of the logistic models with different thresholds were similar, and substantially agreed with the linear model, we only reported the estimates from one model to avoid redundancy. The reported estimates were thus based upon the mixed-effect logistic regression model using 10 “positive” answers as the cutoff. Such a model was chosen because it assured the highest comprehension and balanced the need to reduce potential overfitting, avoid a high overestimation of the strength of the observed associations due to the use of odds ratios (ORs), finally be based upon a threshold indicating a sufficiently high level of adherence

A two-tailed p-value of 0.05 was considered significant for all analyses, which were performed using Stata 10.1 (Stata Corp., College Station, TX, USA, 2007).

Results

Characteristics of the sample and equipment

Fourteen public hospitals from seven regions of Italy accepted to participate, and a total of 1334 questionnaires were collected. The mean age of the sample was 60.0±16.7 years; males were 53.1% (Table 1). Most participants were admitted to departments of Internal Medicine (27.0%), Cardiology (10.1%), General Surgery (9.4%), Cardiovascular surgery (12.0%) and Orthopedics (12.9%). To measure BP, more than two thirds (67.1%) of the units used aneroid devices, which was calibrated in the last six-months in 34.8% of the cases. A replacement bladder arm was available in 38.1% of the units, and the size of the alternative cuff was large or extra-large in most cases (34.8%). According to most participants, it was a nurse or nursing student determining their BP (68.9% and 7.0%, respectively), while physicians and medical students were less frequently involved (6.2% and 10.3%, respectively). Interestingly, only 7.6% of the patients were not sure of the profession of the BP evaluator.

Adherence to guidelines – Quality of blood pressure measurement

As shown in Table 2, nine of the recommended practices were followed in the majority (>70%) of BP recordings, while some others were infrequent or even rare. In particular, the arm circumference was almost never assessed during the hospital stay (1.4%); BP was recorded only once in 82.2% of the participants; BP was never measured in both arms in 81.1% of the patients, and in most cases (≅71.3%) the operators did not explain the procedure and did not ask whether the patient ate or drank caffeine or he was anxious before the measurement. Finally, the patient was kept resting for >=5 minutes in half of the cases.

Overall, at least 8 of the 15 selected procedures were followed during 70.9% of the BP measurements; at least 10 procedures during 33.4% recordings, and all of the 15 recommended procedures were never adopted.

Predictors of adherence to guidelines

Multivariate analysis substantially confirmed univariate results, showing that physicians were significantly less likely than nurses to adhere to at least ten of the selected recommended procedures (OR 0.50; 95% Confidence Interval – CI: 0.25-0.97) (Table 3). Moreover, compared with patients treated in Internal Medicine, those admitted in General Surgery of other Surgical Specialties were less likely to experience a higher-quality BP recording (OR=0.38; 95% CI: 0.21-0.68, and OR=0.43; 95% CI: 0.25-0.75, respectively).

Comment

Several studies documented a large discrepancy in BP when assessed with standardized or casual techniques [7, 9, 14, 19]. In fact, even minor errors in BP measurement can lead to the misclassification of millions of persons, with consequent negation or suspension of therapy for hypertensive patients or, vice versa, needless exposure of normotensive people to treatment expenses and adverse effects [4]. Despite the relevance of the topic from a public health standpoint, few studies assessed the accuracy of BP determination in real practice, reporting concordant, discouraging results [15-19]. Both calibration and maintenance of devices were often irregular [5, 16, 17], and current guidelines for patient preparation and measurement technique were infrequently followed [15-19].

The results of this study were not univocal: although some of the recommended procedures for BP determination were followed by the vast majority of health professionals (silent patient and room, use of back and arm supports, correct arm and cuff positioning, no cloths over cuff), the operator's compliance to some other recommendations was unacceptably low. First, more than 60% of the units were only equipped with regular-size cuff, and less than 2% of the participants had their arm circumference measured during the admission (with the best hospital averaging below 10%). Apparently, operators are not aware that larger cuffs could be needed for 25%-30% of the Italian population [24] and that the use of regular cuffs for overweight/obese/muscle patients causes consistent overestimation of diastolic BP by approximately 6 mmHg [25].

Second, less than 20% of the operators recorded BP in both arms at least once during the hospitalization. Besides guidelines, a recent meta-analysis found a higher risk of vascular disease and death in patients with a ≥10 mmHg BP difference between arms, confirming the importance of this practice to detect patients needing further vascular assessment [10].

Third, BP was measured only once in more than 82% of the patients (with the best hospital approaching 36%). Although partially expected, this finding is particularly disappointing because the white coat effect and biological variability are known since decades [3, 5], and because recent studies observed a difference in systolic BP ≥10 mmHg across temporally close measurements in 30% of the subjects [2], and a 40% probability of hypertension misdiagnosis with a single measurement [1].

Fourth, an explanation of the process and questions on BP influencing behaviors (such as smoking or drinking coffee) or psychological statuses (i.e. irritation) were made to less than one third of the participants, and the typical 5-minute rest was assessed in less than half of the patients. However, these deviations from current recommendations may rise fewer concerns because into an inpatient setting they may be assumed as infrequent by operators (except nervousness).

Taken together, the above results suggest that the compliance to current recommendations widely differ across single procedures, the degree of inaccuracy in BP measurement seems however unacceptably large, in line with previous literature reporting an overall negative scenario. The potential explanations are simple and well known: time shortage [6, 8], lack or insufficient formal training on BP measurement [17, 26] and, most probably, on the implications of inaccurate determination of BP. Although longer time for visiting is a

difficult target to obtain, educational programs are certainly affordable and, especially if specifically targeted to the most frequent errors, they might achieve important results even in the short term. This survey provided some important insights for decision makers and medical directors on which priorities to set in their training courses (both arms should be considered at least once; two or more recordings must be taken; arm circumference should be measured). Also, we identified some independent predictors of inaccurate measurement: according to our findings, the initial actions should be targeted to physicians and to the personnel of surgical units (excepted Cardiovascular Surgery). Finally, educational programs should not be limited to measurement procedures but also explain why following current guidelines might be important for the patient (i.e. how largely triplicate readings may reduce the effect of BP measurement inaccuracies [1, 20]). Given this, education alone is unlikely to entirely solve the problem, and some experts advocated a regulatory approach in which professional organizations include BP measurement as a performance metric [4, 8]. Also, the present survey was relatively simple and inexpensive, and had very little impact on patients and hospital staff. As an initial intervention to raise the awareness of operators, surveys like the present could be carried out on a regular basis both in hospital and primary care settings.

This study has some limitations that must be taken into consideration. First, because of the cross-sectional design of the study, we could not determine causal relationships but only associations in the analysis of the predictors of BP measurement accuracy. Second, although we enrolled a large number of subjects from several Italian regions and public hospitals of various sizes, we were not able to enroll private hospitals and the sample was not derived using a randomized multi-stage sampling technique. Thus, the sample cannot be considered representative of the overall population of Italian hospital patients. As an example, more than half of our sample come from large academic reference hospitals. Therefore, the level of accuracy of BP measurement might be overestimated, and results cannot be extrapolated to the entire Italian inpatient context. On the other side, however, it must be noted that when the worst and best hospitals were excluded, the results of single hospitals were quite homogeneous and close to the average, suggesting that the observed scenario may be widespread throughout the Italian public hospital system.

Third, despite the multivariate analysis accounted for the cluster effect of region and hospital, we only considered a limited number of selected predictors of accuracy and several others might be present (i.e. diabetes or body mass index).

Fourth, we assessed BP recording accuracy from the patient, who might have been motivated to a more critical approach by the survey. However, we believe that this may rather be a strength of the study, as the commonly used alternative – asking to health professionals – is likely to be affected by an even larger reporting bias. Besides, according to the World Alliance for Patient Safety, a primary focus of every WHO region should be the establishment of a repository of patient reported information [27].

In conclusion, several of the recommended procedures for the determination of BP were strictly followed by most of the health professionals of this sample of Italian hospitals, but some major deviations from acceptable standards were very common and consistent across hospitals and regions. In particular, patient's arm circumference was almost never measured, BP was infrequently recorded in both arms, and it was measured only once in most subjects. Nurses were more accurate in determining BP than physicians, and more errors were observed in surgical units. Although a certain degree of inaccuracy could be tolerated into an inpatient setting, where some factors including pain, anxiety or acute therapies may hamper a precise assessment of BP, our results suggest that the importance of accurate BP measurement is largely ignored, and more attention to the topic is strongly needed.

Author Contributions: All authors participated in the design, data collection and interpretation of the study. LM, GC and CP were involved in all phases of the study. LM and MEF made the statistical analysis. LM, GC and CP wrote the manuscript. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Acknowledgements

Authors gratefully acknowledge the collaboration of the following nurses and physicians, the support of whom was essential for data collection: Enzo Giannattasio, Antonietta Greco, Giuliana Nervuti, Carmela Trofa, Tania Sabattini, and Marina Zoli.

Funding/Support: None

Financial Disclosure: None

Table 1. Overall characteristics of the sample (n=1334).

Variables	**Overall sample**
Male gender, %	53.1
Mean age in years (SD)	60.0 (16.7)
Region, %	
Abruzzo	21.6
Campania	7.1
Emilia-Romagna	17.7
Lazio	13.3
Marche	21.6
Piedmont	14.8
Tuscany	3.9
Hospital ward, %	
- Internal Medicine	27.0
- Cardiology	10.1
- Cardiovascular Surgery	9.4
- General Surgery	12.0
- Orthopedics	12.9
- Geriatrics	5.2
- Pulmonary Medicine	3.9
- Obstetrics and Gynecology	6.2
- Urology	4.1
- Other surgical specialties	6.0
- Other non-surgical specialties	3.2
*Type of device to measure BP *, %*	
- Mercurial	4.6
- Aneroid	67.1
- Electronic, automatic	18.0

- Electronic, semi-automatic	2.4
- Electronic, manual	7.8
*Device calibration update *, %*	
- More than 6 months before	47.3
- Less than 6 months before	34.8
- Not known	17.9
*Type of replacement cuff available *, % ** *	
- None	61.9
- Pediatric	2.2
- Adult	13.8
- Adult, large or extra-large	34.8
Personnel who measured BP, %	
- Nurse	68.9
- Physician	6.2
- Nursing student	7.0
- Medical student	10.3
- Not known	7.6

* Measured by the interviewer. ** More than one answer possible.

Table 2. Adherence to guidelines for the measurement of blood pressure (BP) in the sample (n=1334).

Items	**Yes,** %	(95% CI)	**Worst-Best Hospital**, %
1. Before BP measurement, did the operator explain the procedure?	28.8	(26.4-31.2)	0-83
2. Before BP measurement, did you rest for at least 5 minutes?	49.1	(46.4-51.8)	0-84
3. Before BP measurement, did the operator ask whether in the last hour you smoked, ate or drunk caffeine or made some physical activity or efforts (i.e. climbing stairs), or you were nervous?	28.6	(26.1-30.9)	0-96
4. During your stay, before BP measurement, did the operator measure your arm circumference at least once?	1.4	(0.8-2.1)	0-9
5. During your stay, did the operator measure your BP in both arms at least once?	18.9	(16.8-21.1)	0-44
6. During your stay, were BP measurement made always in the same body position, or sometimes they were made in different positions (i.e. sitting then lying or vice versa)?			
- Always in the same position	70.7	(68.2-73.1)	33-87
7. During the hospital stay, did operators always measured your BP at the same hour (i.e. in the morning/fasting, or in the afternoon after lunch)?	61.2	(58.6-63.9)	26-91
8. Did the operator measure your BP only once, or did he/she repeat the measurement after some minutes?			
- He/she repeated the measurement after some minutes	17.8	(15.8-19.9)	0-36
9. During BP measurement, was the room calm, with low noise, and no distractions (people talking, radio/television on, etc.)?	77.2	(74.9-79.5)	29-100

10. During BP measurement, were you silent?	92.7	(91.3-94.1)	82-100
11. During BP measurement, was your back supported by the chair or bed saddle?	87.1	(85.3-88.9)	68-100
12. During BP measurement, was your arm supported (i.e. on a table if you were sitting, or on the bed if outstretched)?	86.2	(84.3-88.1)	48-98
13. During BP measurement, was your arm positioned at the same height of your heart?	75.1	(72.7-77.4)	34-100
14. During BP measurement, was the point where the bladder arm was located uncovered?	93.6	(92.3-94.9)	83-100
15. During BP measurement, did the operator posed two fingers on your wrist to perceive heart rate (as shown into a Figure)?	75.2	(72.9-77.6)	62-100
Overall pattern			
Eight or more positive answers to the above questions	70.9	(68.4-73.3)	38-98
Ten or more positive answers to the above questions	33.4	(30.8-35.9)	0-77
Twelve or more positive answers to the above questions	8.7	(7.2-10.2)	0-22

Table 3. Potential predictors of higher-quality * blood-pressure (BP) measurement.

	Higher-quality BP measurement		
Variables	**Crude OR (95% CI)**	**Adjusted OR (95% CI) ****	**p ****
Age, 1-year increase	1.01 (1.00-1.01)	1.01 (1.00-1.02)	0.06
Male gender	0.77 (0.58-1.01)	0.92 (0.69-1.25)	0.6
Personnel who measured BP			
- Nurse (Ref. cat.)	1	1	--
- Physician	0.44 (0.23-0.85)	0.50 (0.25-0.97)	0.040
- Nursing student	1.00 (0.62-1.61)	1.14 (0.61-2.12)	0.7
- Medical student	1.12 (0.30-4.11)	1.08 (0.29-4.09)	0.9
Hospital ward, %			
- Internal Medicine (Ref. cat.)	1	1	--
- Cardiology	0.92 (0.51-1.66)	0.84 (0.46-1.53)	0.6
- Other non-surgical specialties ***	1.47 (0.89-2.43)	1.29 (0.75-2.24)	0.4
- General Surgery	0.37 (0.22-0.63)	0.38 (0.21-0.68)	0.001
- Cardiovascular Surgery	0.76 (0.44-1.32)	0.82 (0.46-1.49)	0.5
- Orthopedics	2.03 (0.92-4.48)	1.95 (0.86-4.42)	0.11
- Other surgical specialties ****	0.36 (0.22-0.60)	0.43 (0.25-0.75)	0.003

CI = Confidence Interval. * At least ten positive answers to the fifteen items of the questionnaire (see Table 2 for details). ** Random-effect logistic regression model, using Region as the cluster unit. * Including geriatrics and pulmonary medicine. **** Including urology and obstetrics and gynecology.

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